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TITLE: Treating Gulf War Illness with Novel Anti-Inflammatories: A Screening of Botantical Microglia Modulators

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14. ABSTRACT

On June 30, 2015, we obtained final IRB approval and an IND exemption determination from UAB IRB. All approved documents (consent form, human subject protocol and attachments) were forwarded to ORP HRPO for final approval on July 2, 2015.

While awaiting final ORP HRPO approval we have worked to establish collaborations with Birmingham and Alabama VA support groups for recruitment purposes. We have also established a great rapport with the nursing staff at the UAB Clinical Research Unit (CRU) where the study will be conducted. We have selected personnel to run the study and started training on the UAB IRB process, regulatory document preparation, review and submission.

Upon the receipt of the final IRB ORP HRPO approval, we will initiate recruitment advertising, participant screening, enrollment and the study protocol.

15. SUBJECT TERMS
Gulf War Illness, botanical, anti-inflammatory, biomarker, microglia, improvement, treatment

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1. **INTRODUCTION:**

The major aim of this research project is to identify the most promising botanical anti-inflammatories for the treatment of Gulf War Illness (GWI). A second, exploratory, aim is to identify biomarkers of GWI improvement. To accomplish those aims at UAB, we are recruiting 40 male veterans diagnosed with Gulf War Illness (GWI). Each participant will receive 3 different botanical compounds and placebo over a 300 day period. Each participant will also participate in a 30-day baseline period starting the first month to report their individual daily GWI symptom severity ratings. Analyses will then be conducted to identify the most effective botanical compound that reduced microglia hyper excitability. Ultimately, this information may be used to develop new treatments that specifically target the pathophysiological mechanisms of Gulf War Illness.

2. **KEYWORDS:**

Gulf War Illness, botanical, anti-inflammatory, biomarker, microglia, improvement, treatment

3. **ACCOMPLISHMENTS:**

(Note: We have successfully completed the institutional transfer from Stanford University to the University of Alabama at Birmingham-UAB. A revised SOW was submitted on September 24, 2014).

Current Objectives:

· Begin participant enrollment

· Begin the protocol and data collection

Task 1: Team review and progress meetings

25% Completed.

(Note: Final approval from USAMRMC ORP HRPO is on-going; upon final approval receipt participant enrollment will begin. The final meeting before starting the study protocol and medical reviews will be scheduled after ORP HRPO approval has been received. The completion of Task 1 *Milestones: Agreement on eligibility criteria, screening protocol and procedure; Consent form and human subjects protocol finalized* are dependent upon receipt of ORP HRPO final approval).

Task 2: Submission of Documents for Regulatory Approvals

100% Completed.

(Note: UAB IRB approval was received June 30, 2015 and all approved documents were submitted to USAMRMC ORP HRPO on July 2, 2015 for approval).

Task 3: Start up

30% Completed. We have selected the personnel to run the project.

(Note: The completion of Task 3 and *Milestone: Study protocol ready to begin* is dependent upon receipt of ORP HRPO final approval. Also, the purchase and blinding of the treatment compounds, scheduling the mock session and creation of the trial database /randomized lines will begin upon receipt of the ORP HRPO final approval).

Task 4: Advertisement

0% Completed. Task progress is dependent on the completion of Task 3.

(Note: The initiation of Task 4 and *Milestone: 120 potential participants screened by telephone* are dependent upon the receipt of ORP HRPO final approval).

Task 5: Screen GWI participants for study

0% Completed. Task progress is dependent on the initiation of Task 4.

(Note: The completion of Task 5 *Milestone: First participant enrolled* is dependent upon the receipt of ORP HRPO final approval).

Task 6: Run protocol

0% Completed. Task progress is dependent on the initiation of Task 5 and participant enrollment.

Task 7: Assays

0% Completed. Task progress is dependent on the completion of Tasks 5 & 6.

Task 8: Analysis

0% Completed. Task progress is dependent on the completion of Task 6 &7.

Task 9: Preparation of Final report and Publications

0% Completed. Task progress is dependent on the completion of Tasks 6, 7, & 8.

4. **IMPACT:**

Nothing to report

5. **CHANGES OR PROBLEMS:**

We are currently awaiting final IRB approval from ORP HRPO. Upon receipt of that final approval, advertising for recruitment, participant screening and enrollment will begin. We anticipate enrollment will begin by mid-January 2016.

6. **PRODUCTS:**

Nothing to report.

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:**

Name	Jarred Younger
Project Role	PI
Research Identifier	
Nearest person month worked	1.7 CM
Contribution to Project	Dr. Younger has prepared & reviewed documents for submission to UAB to complete the grant transfer process from Stanford University to UAB; and also to receive UAB IRB & ORP HRPO final approval. Dr. Younger has met with local VA support group leaders in an effort to establish a recruiting collaboration.

Name	Lisa Smoot
Project Role	Coordinator
Research Identifier	
Nearest person month worked	2.3 CM
Contribution to Project	Lisa has assisted Dr. Younger with the preparation, review and submission of documents to UAB to complete the grant transfer process from Stanford University to UAB; to receive final UAB IRB for approval. She has also forwarded UAB approved and requested documents to ORP HRPO for their final IRB approval. Lisa has identified local VA support groups and met with leaders to establish recruiting methods to initiate upon receipt of final ORP HRPO approval.

8. **SPECIAL REPORTING REQUIREMENTS:**

None.

9. **APPENDICES:**

None.